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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/518,297	03/03/2000	Moon Young Lim	4600-0130.30	5390

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 09/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/518,297

Applicant(s)

LIM ET AL.

Examiner

Chih-Min Kam

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 30 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 6,9,10,12,18,19,21-26 and 34-39 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

- 5) ☒ Claim(s) 9,10,18 and 19 is/are ~~allowed~~ *free of art*.

- 6) ☒ Claim(s) 6,12,21-26 and 34-39 is/are rejected.

- 7) ☐ Claim(s) _____ is/are objected to.

- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

DETAILED ACTION

Status of the Claims

1. Claims 6, 9, 10, 12, 18, 19, 21-26 and 34-39 are pending.

Applicants' response filed June 30, 2003 (Paper No. 20) is acknowledged, and applicants' response has been fully considered. Claims 6, 9, 10, 12, 19, 21 and 23-26 have been amended, claims 1-5, 7-8, 11, 13-17 and 27-30 have been cancelled, and new claims 34-39 have been added. Therefore, claims 6, 9, 10, 12, 18, 19, 21-26 and 34-39 are examined.

Objection Withdrawn

2. The previous objection of claims 6, 9, 10 and 21-26 is withdrawn in view of applicants' amendment to the claim, and applicants' response at page 10 in Paper No. 20.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

3. The previous rejection of claims 2, 12 and 19, under 35 U.S.C.112, second paragraph, is withdrawn in view of applicants' cancellation of the claim, applicants' amendment of the claim, and applicants' response at page 9 in Paper No. 20.

Claim Rejections - 35 USC § 102

4. The previous rejection of claims 1-5, 7, 8, 11, 13-17 and 27-30 under 35 U.S.C. 102(b) as being anticipated by Goldstein *et al.* (U. S. Patent 5,527,690), is withdrawn in view of applicants' cancellation of the claim, and applicants' response at page 9 in Paper No. 20.

Claim Objections

5. Claim 12 is objected to because the claim recites part (iv), which has already been included in part (iii).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is indefinite because the claim cites part (iv) of a first nucleic acid construct is a second nucleic construct and the DNA binding compound, it is not clear how a nucleic acid construct contains a DNA binding compound, and whether a second nucleic acid construct is in the first nucleic acid construct or in the molecular switch.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 6, 12, 21-26 and 34-39 are rejected under 35 U.S.C. 102(b) as being anticipated by Bujard *et al.* (WO 94/29442).

Bujard *et al.* teaches a system for regulating expression of eucaryotic genes using components of the Tet repressor/operator/inducer system of prokaryotes in a host cell, and

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transcription of a nucleotide sequence operably linked to at least one tet operator sequence is stimulated by a tetracycline (Tc)-controllable transcriptional activator fusion protein (tTA) which comprises two polypeptides, the first polypeptide is a Tet repressor (TetR), which binds to tet operator sequence in the absence of Tc (claims 21, 22, 25 and 26), and the second polypeptide directly or indirectly activates transcription in eucaryotic cells, e.g., the second polypeptide can be a transcriptional activation domain from herpes simplex virus viron protein 16 (VP16) (page 2, lines 4-14; claims 23 and 24), where in the absence of Tc, transcription of a gene operably linked to a tTA-responsive promoter (typically comprising at least one tet operator sequence and a minimal promoter) is stimulated by a tTA (page 2, lines 17-21). The reference also indicates a host cell can contain a polynucleotide moiety encoding a tTA and a gene of interest operably linked to a tTA-responsive transcriptional promoter, where the gene of interest operably linked to the tTA-responsive transcriptional promoter can be integrated into DNA of the host cell either randomly (e.g., by introduction of an exogenous gene) or at a predetermined location (e.g., by targeting an endogenous gene for homologous recombination, the integration of polynucleotide encoding tTA and a tTA-responsive promoter, page 3, lines 24-39; claims 6, 12 and 34-39), and expression of a gene of interest operably linked to a tTA-responsive transcriptional promoter in a host cell can be inhibited by contacting the cell with Tc (page 4, line 1-31; page 12, lines 19-37). The tTA acts not only as a transcriptional regulatory protein but also as DNA binding compound.

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Conclusion

7. Claims 6, 12, 21-26 and 34-39 are rejected. It appears claims 9, 10, 18 and 19 are free of prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (703) 308-9437. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, Ph. D. can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-0294 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Chih-Min Kam, Ph. D. *CYK*
Patent Examiner

September 15, 2003

Christopher S. F. Low
CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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